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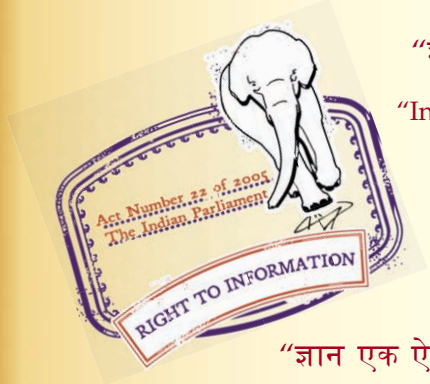

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SPECIFICATION FOR GLASS TUBES FOR MEDICAL THERMOMETERS

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Indian Standard

SPECIFICATION FOR GLASS TUBES FOR MEDICAL THERMOMETERS

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 29 January 1968, after the draft finalized by the Laboratory Glassware and Related Apparatus Sectional Committee had been approved by the Chemical Division Council.

0.2 Medical thermometers are being manufactured in the country on a large scale. 'Indian Standard specification for clinical thermometers' (IS : 3055-1965) has already been published and specifications for other medical thermometers are under preparation. Since glass tubes, the basic raw material for the manufacture of such thermometers, have to be of a specific type, the Laboratory Glassware and Related Apparatus Sectional Committee decided to prepare this standard.

0.3 The object of this standard is to enable manufacturers of medical thermometers to select glass tubes of the right type for producing quality thermometers.

0.3.1 A separate standard is being prepared for glass tubes for general purpose and reference thermometers.

0.4 This standard has clause **5.5.1** which provides for agreement between the purchaser and the supplier.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for glass tubes used in the manufacture of glass type medical thermometers, including veterinary thermometers.

*Rules for rounding off numerical values (*revised*).

2. TERMINOLOGY

2.1 For the purpose of this standard the definitions given in IS : 1382-1961* and IS : 2627-1963†, in addition to the following shall apply.

2.2 **Glass Tubes** — capillary tubes and bulb tubes.

3. SHAPE

3.1 The shape, that is, the cross-section of the capillary tubes shall be prismatic having a lens front as shown in Fig. 1.

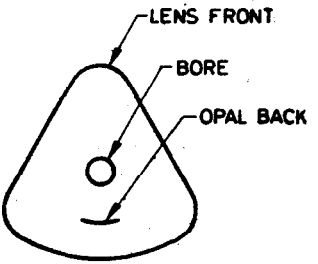

FIG. 1 CROSS-SECTION OF CAPILLARY TUBES OF MEDICAL THERMOMETERS

3.2 The bulb tubes shall be of circular cross-section.

4. MATERIAL

4.1 **Appearance** — Glass capillary and bulb tubes shall be of clear, transparent glass free from occlusions, striae, stresses and other visual defects such as bubbles, double bore, knots, reflection failures and roughness of the bore.

4.1.1 The capillary tubes shall be provided with a white or yellow back.

NOTE — Additional coloured glass strip or strips may be provided suitably on the capillary tubes.

4.2 The capillary tubes shall not have (a) any double bore at the two ends as viewed through a microscope having minimum magnification of 250 times, and (b) any angular twist as measured by change in the apparent width of the bore as seen by a plastic scale.

4.3 The lens front of the capillary tubes shall magnify the mercury column in the bore to a width of at least one millimetre (*see* 4.3.2.1 of IS : 3055-1965‡).

*Glossary of terms relating to glass industry.
†Glossary of terms relating to liquid-in-glass thermometers.
‡Specification for clinical thermometers.

4.4 The bulb tubes shall not have any stone or air line visible to the naked eye.

5. REQUIREMENTS

5.1 The tubes shall not devitrify during two heatings for three minutes at a stretch in an oxidizing flame of a burner.

5.2 Coefficient of Linear Thermal Expansion — The average coefficient of linear thermal expansion of the tubes shall be $8{\cdot}5 \pm 0{\cdot}3 \times 10^{-6}$ per deg in the range of 0° to 100°C.

5.2.1 The difference in the coefficients of linear thermal expansion of the capillary tubes and the bulb tubes shall not be more than $0{\cdot}2 \times 10^{-6}$ per deg.

5.2.2 The coefficient of linear thermal expansion of opal glass, used for providing backing and coloured strips, shall be such that it does not shatter when the capillary tubes are heated repeatedly as given in **5.1.**

5.3 Stability of Bulb Tubes — The bulb tubes shall be considered stable if a special thermometer, having a range 0° to 100°C, made with that bulb tubing without a maximum indicating device, complies with the following requirements:

a) The zero shall not rise more than 0·02 deg in the first six months of the manufacture of the thermometer, and

b) After ageing, the zero depression after heating the thermometer at 100°C for one hour, shall not exceed 0·05 deg.

5.4 Limit of Alkalinity — When graded according to the method prescribed in IS : 2303-1963*, glass tubes shall conform to Type 5 of the glass.

5.5 Dimensions

5.5.1 *Length* — The length of glass tubes shall be as agreed to between the purchaser and the supplier.

5.5.2 *Diameter* — The diameter of the capillary tubes shall be not less than 4 mm and not more than 6 mm when measured with a ring gauge or a shadow graph.

5.5.2.1 The outside diameter of the bulb tubes shall be between 2 and 3·5 mm for use in oral, and 3 and 5 mm for use in rectal, stubby or veterinary thermometers when measured with a ring gauge or a shadow graph.

*Method of grading glass for alkalinity.

5.5.3 *Bore*

5.5.3.1 The shape of the bore of the capillary tubes shall be circular or elliptical. If elliptical, the ratio of the major axis to the minor shall be not more than 2·5.

5.5.3.2 The bore area of the capillary tube for use in oral thermometers shall be not less than 0·000 3 mm^2 and not more than 0·003 m^2, while for use in rectal stubby or veterinary thermometers, it shall be not less than 0·000 4 mm^2 and not more than 0·004 mm^2 when measured, at each end, with a high power microscope having a magnification of not less than 250 times or any other suitable instrument.

5.5.3.3 The bore area at any end shall not differ from the average of the two bore areas by more than 5 percent.

5.5.3.4 The shape of the bore of the bulb tubes shall be circular.

6. PACKING AND MARKING

6.1 Packing — Glass tubes shall be packed in sealed polyethylene bags free from moisture, dirt and dust. The bags shall be packed in suitable cardboard boxes. Alternately, each tube shall be flame sealed at both ends.

6.2 Marking

6.2.1 Each bag shall be marked with the following information:

a) Name of the material;

b) Manufacturer's name or recognized trade-mark, if any;

c) Lot number to enable the batch of manufacture to be traced from records;

d) Year of manufacture;

e) Bore area and its tolerance, and

f) Accelerated ageing schedule recommended by the manufacturer.

6.2.2 The packages may also be marked with the ISI Certification Mark.

NOTE — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

7. SAMPLING

7.1 Representative samples of the material shall be drawn and adjudged as prescribed in Appendix A.

APPENDIX A

(*Clause* 7.1)

SAMPLING OF GLASS TUBES FOR MEDICAL THERMOMETERS

A-1. SCALE OF SAMPLING

A-1.1 Lot — In a single consignment all the capillary tubes with the same type and size of bore (or all the bulb tubes for the same type of thermometers produced in the same batch of manufacture) shall constitute a lot.

A-1.2 Samples shall be tested from each lot separately for ascertaining conformity of the tubes in the lot to the requirements (except stability of bulb tubes) of this specification.

A-1.3 The number of sample tubes to be selected for testing shall depend on the size of the lot and shall be in accordance with Table 1 when the lot contains up to 1 000 tubes and in accordance with Table 2 when the lot contains more than 1 000 tubes.

TABLE 1 SCALE OF SAMPLING FOR LOTS CONTAINING UP TO 1 000 TUBES

Lot Size	Sample Size	Acceptance Number
(1)	(2)	(3)
Up to 300	20	0
301 to 1 000	80	1

A-1.4 Random Selection — The tubes shall be selected at random from the lot. In order to ensure rendomness of selection random number tables shall be used. In case random number tables are not available, the following procedure may be adopted:

Starting from any item count them as 1, 2, 3,....., etc, up to r and so on in one order. Every rth item thus counted shall be chosen for the sample, where r is the integral part of N/n, N being the total number of items and n the number to be chosen.

TABLE 2 SCALE OF SAMPLING FOR LOTS CONTAINING MORE THAN 1 000 TUBES

(*Clause* A-1.3)

Lot Size	Sampling Stage	Sample Size	Cumulative Sample	Acceptance Number	Rejection Number
(1)	(2)	(3)	(4)	(5)	(6)
Above 1 000	First	20	20	*	2
	Second	20	40	*	2
	Third	20	60	0	2
	Fourth	20	80	0	3
	Fifth	20	100	1	3
	Sixth	20	120	1	3
	Seventh	20	140	2	3

*Acceptance not permitted at this stage.

A-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY FOR LOTS CONTAINING UP TO 1 000 TUBES

A-2.1 Sample tubes, as required in col 2 of Table 1, shall be selected from the lot in two steps. In the first step at least 50 percent of the bags in the lot shall be taken at random. Then in the second step from each selected bag an equal number of tubes shall be taken at random so as to give the total number of tubes in accordance with col 2 of Table 1.

A-2.2 Requirements Other Than Alkalinity — All the sample tubes shall be individually tested for all the requirements except that of alkalinity. Any tube which fails to satisfy any one or more of these requirements shall be called a defective.

A-2.2.1 If the number of defectives in the sample tubes does not exceed the acceptance number specified in col 3 of Table 1 the lot shall be declared to conform to these requirements and shall be passed on for alkalinity test (*see* **A-2.3**).

A-2.3 Alkalinity Requirement — The lot having been found to conform to all other requirements in **A-2.2**, shall be tested for alkalinity. For this purpose, from the sample tubes, a number of tubes shall be taken at random so as to yield after crushing an adequate quantity of glass for one alkalinity test.

A-2.3.1 If the result of alkalinity test meets the specified alkalinity requirement, the lot shall be declared as conforming to the requirements of this specification.

A-3. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY FOR LOTS CONTAINING MORE THAN 1 000 TUBES

A-3.1 The sample tubes shall be selected at random from the lot in stages at the rate of 20 per stage according to need as in **A-3.2.**

A-3.2 Requirements Other Than Alkalinity — Testing and judging conformity for these requirements shall be done stage-by-stage as follows:

First Stage — Twenty sample tubes shall be taken at random from as many bags in the lot as possible. Each of the 20 tubes shall be tested for these requirements. A tube which fails to satisfy any one or more of these requirements shall be called defective. If the number of defectives found in these 20 tubes equals or exceeds the rejection number corresponding to the first stage in Table 2, the lot shall be rejected without further testing, otherwise testing shall proceed to the second stage.

Second Stage — In the second stage 20 more tubes shall be taken from the lot at random from as many bags as possible and representing as many new bags as possible. Each of these 20 tubes shall be tested for these requirements. If the total number of defectives of both the stages equals or exceeds the rejection number corresponding of the second stage in Table 2, the lot shall be rejected without further testing, otherwise testing shall proceed to the third stage.

Third Stage — In this stage 20 more tubes shall be taken from the lot at random from as many bags as possible and representing as many new bags as possible. Each of these 20 tubes shall be tested for these requirements. If the total number of defectives of all the stages so far is equal to or less than the acceptance number corresponding to this stage in Table 2 the lot shall be declared to conform to these requirements; if it is equal to or greater than the rejection number corresponding to this stage in Table 2 the lot shall be rejected; if it is in between the corresponding acceptance number and the rejection number the testing shall proceed to the next stage.

Fourth and Subsequent Stages — The procedure for the fourth and the subsequent stages, if needed, shall be the same as for the third stage till a decision to reject or to accept the lot for these requirements is reached.

A-3.3 Alkalinity Requirement — The lot having been found to conform to all other requirements in **A-3.2**, shall be tested for alkalinity. For this purpose two alkalinity determinations shall be made; one from the sample tubes of the first stage and the other from the sample tubes of the second stage. The tubes for alkalinity test shall be taken at random from the stage sample so as to yield after crushing an adequate quantity of glass for one test.

A-3.3.1 If the two test results for alkalinity separately meet the specified alkalinity requirement, the lot shall be declared as conforming to the requirements of this specification.

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